**UNITED STATES DISTRICT COURT**
**DISTRICT OF MINNESOTA**

Schwarz Pharma, Inc., Schwarz Pharma AG, and Warner-Lambert Company, LLC,

Plaintiffs,

v.

Paddock Laboratories, Inc.,

Defendant.

**MEMORANDUM OPINION AND ORDER**
Civ. No. 05-832 ADM/JJG

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Brian M. Poissant, Esq. and Gasper J. LaRosa, Esq., Jones Day, New York, NY; and Peter R. Forrest, Esq., Gray, Plant, Mooty, Mooty & Bennett, P.A., Minneapolis, MN, argued on behalf of Plaintiffs.

Michael J. Fink, Esq. and P. Branko Pejic, Esq., Greenblum & Bernstein, P.L.C., Reston, VA; and Daniel C. Bryden, Kelly & Berens, PA, Minneapolis, MN, argued on behalf of Defendant.

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## I. INTRODUCTION

On February 9, 2006, a Markman hearing was held before the undersigned United States District Judge on the patent infringement claim of Schwarz Pharma, Inc. ("SPI"), Schwarz Pharma AG ("SPAG") (SPI and SPAG are collectively "Schwarz Pharma"), and Warner-Lambert Company, LLC ("Warner-Lambert") (all three collectively "Plaintiffs") against Paddock Laboratories, Inc. ("Paddock" or "Defendant"). Also addressed in this Order are Paddock's Motion for Leave to File a Motion for Summary Judgment of Noninfringement [Docket No. 120] and Warner-Lambert's Objections [Docket No. 88] to Magistrate Judge Jeanne J. Graham's Order [Docket No. 86] granting in part and denying in part Defendant's Motions to Compel Discovery [Docket Nos. 60, 65].

## II. BACKGROUND

This lawsuit concerns United States Patent 4,743,450 ("the '450 patent"), entitled "Stabilized Compositions." Pejic Decl. 3d [Docket No. 54] Ex. 1. The '450 patent discloses a pharmaceutical composition that combines Angiotensin Converting Enzyme ("ACE") inhibitors with certain stabilizers that prevent degradation, i.e., cyclization, hydrolysis, and discoloration, to create a medication for treating hypertension and congestive heart failure. Id. Warner-Lambert owns the '450 patent. Compl. [Docket No. 1] ¶ 11. Warner-Lambert granted SPAG an exclusive license to manufacture and sell moexipril hydrochloride[1] products under the '450 patent, which SPAG in turn granted to SPI. Id. ¶ 12. SPI sells drug products containing moexipril hydrochloride under the trademark UNIVASC®. Id.

Paddock is a developer, manufacturer, and seller of generic pharmaceutical products. Countercl. [Docket No. 5] ¶ 1. Paddock submitted an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell tablets containing moexipril hydrochloride prior to the expiration of the '450 patent.[2] Id. ¶ 38; Compl. ¶¶ 13, 14. Paddock sent a Notification Letter to Plaintiffs, informing them of its ANDA and certification that its product does not infringe any claims of the '450 patent. Countercl. ¶ 40; Compl. ¶ 15. Plaintiffs allege that Paddock's filing of its ANDA constitutes infringement of one or more of the claims of the '450 patent. Compl. ¶ 16.

The '450 patent consists of claims 1 through 17. Pejic Decl. 3d Ex. 1. Claims 1 and 16

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[1] Moexipril hydrochloride is an ACE inhibitor.

[2] The '450 patent is listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluation" ("Orange Book") as covering UNIVASC® tablets.

are independent claims, and the remaining claims are dependent on either claim 1 or claim 16. Id. Schwarz Pharma asserts claims 1, 5-8, 12, and 16 of the '450 patent in this action, but only claims 1 and 16 are disputed. Pl.s' Claim Construction Mem. [Docket No. 57] at 5. Claim 1 states:

> 1. A pharmaceutical composition which contains:
> (a) a drug component which comprises a suitable amount of an ACE inhibitor which is susceptible to cyclization, hydrolysis, and discoloration,
> (b) a suitable amount of an alkali or alkaline earth metal carbonate to inhibit cyclization and discoloration, and
> (c) a suitable amount of a saccharide to inhibit hydrolysis.

Pejic Decl. 3d Ex. 1. Claim 16 states:

> 16. A process for stabilizing an ACE inhibitor drug against cyclization which comprises the step of contacting the drug with:
> (a) a suitable amount of an alkali or alkaline earth-metal carbonate and,
> (b) one or more saccharides.

Id.

Prior to the Markman hearing, counsel for the parties prepared a Joint Claim Construction Statement. Schwarz Pharma and Paddock agree that "an alkali or alkaline earth metal carbonate" means "the salt of an alkali metal or alkaline earth metal cation, and a carbonate or bicarbonate anion,"[3] and "the step of contacting the drug" means "mixing the components with one another." Joint Claim Construction Statement [Docket No. 51]. Schwarz Pharma and Paddock disagree over the meaning of the following terms in claim 1:

- "a drug component which comprises a suitable amount of an ACE inhibitor which

[3] In its opening brief, Paddock asks the court to "clarify" the "scope" of the term "an alkali or alkaline earth metal carbonate" despite Paddock and Schwarz Pharma's agreement as to the meaning of that term, as stated in their Joint Claim Construction Statement. Because the parties have agreed to the meaning of that term, the Court declines to construe this term in a manner different from the agreed construction.

is susceptible to cyclization, hydrolysis, and discoloration,"

- "a suitable amount . . . to inhibit cyclization and discoloration," and
- "a suitable amount . . . to inhibit hydrolysis."

Id. Schwarz Pharma and Paddock disagree over the meaning of the following terms in claim 16:

- "a process for stabilizing,"
- "a suitable amount of," and
- "one or more saccharides."

Id.

On June 30, 2005, Paddock filed its first Motion for Summary Judgment [Docket No. 12]. On July 28, 2005, Magistrate Judge Arthur J. Boylan[4] ordered Paddock's Motion for Summary Judgment stricken as premature. Pretrial Scheduling Order [Docket No. 34]. Judge Boylan further ordered "[d]ispositive motions shall not be filed by either party before the end of the discovery period unless application is made to the court and approval is granted." Id. Paddock next filed an Appeal [Docket No. 35] of Judge Boylan's decision. On September 1, 2005, this Court issued an Order [Docket No. 46] denying Paddock's appeal and affirming Judge Boylan's Order. The Court held that the intent of the Hatch-Waxman Act, the lack of temporal limitations in Fed. R. Civ. P. 56(b), and judicial efficiency concerns do not provide a basis for the Court to find that Judge Boylan's Order was clearly erroneous or contrary to law. The Court further held that if Paddock received FDA approval before the close of discovery, Paddock could petition the Court for leave to file a summary judgment motion. Order at 6. On January 25,

[4] This case was initially assigned to Magistrate Judge Boylan but was later reassigned to Magistrate Judge Graham.

2006, Paddock filed a Motion for Leave to File a Motion for Summary Judgment.

On December 21, 2005, Magistrate Judge Graham issued an Order granting in part and denying in part Defendant's Motions to Compel Discovery. Warner-Lambert objects to the portion of Judge Graham's Order that requires Warner-Lambert to respond to Defendant's requests for admission. Judge Graham Order ¶ 10.

## III. DISCUSSION

### A. Claim Construction[5]

#### 1. Standard of Review

Claim construction is a matter of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995), aff'd, Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996). In construing claims, courts should look first to intrinsic evidence, which includes the claims, the specification, and the prosecution history. Vitrionics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). Claim words are given their ordinary and customary meaning, which "is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Phillips v. AWH Corp., 415 F.3d 1303, 1312-13 (Fed. Cir. 2005). However, a patentee can choose to be "his or her own lexicographer by clearly setting forth an explicit definition for a claim term." Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed. Cir. 1999). Claim terms "should be construed consistently with [their] appearance in other places in the same claim or other claims of the same patent." Rexnord Corp. v. The Laitram Corp., 274 F.3d 1336, 1342

[5] Warner-Lambert contends it is an involuntary plaintiff in this action, and therefore has not participated in the claim construction process. See Joint Claim Construction Statement at 1, nn.1, 2.

(Fed. Cir. 2001). In addition, the specification is usually "dispositive; it is the single best guide to the meaning of a disputed term." Vitrionics, 90 F.3d at 1582. Courts are nonetheless cautioned not to import limitations from the specification into the claims. Phillips, 415 F.3d at 1323; The Laitram Corp. v. NEC Corp., 163 F.3d 1342, 1347 (Fed. Cir. 1998).

Extrinsic evidence is "evidence which is external to the patent and file history, such as expert testimony, inventor testimony, dictionaries, and technical treatises and articles." Vitrionics, 90 F.3d at 1584. While courts can consider extrinsic evidence to educate themselves about the patent and technology at issue, it is improper to rely on extrinsic evidence in construing claims unless, after consideration of all the intrinsic evidence, ambiguity remains. Mantech Envtl. Corp. v. Hudson Envtl. Servs., Inc., 152 F.3d 1368, 1373 (Fed. Cir. 1998); Vitrionics, 90 F.3d at 1584. Dictionaries may be useful to courts in understanding the ordinary and customary meaning of words, and courts may "rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." Phillips, 415 F.3d at 1322-23.

**2. "A Drug Component which Comprises a Suitable Amount of an ACE Inhibitor which is Susceptible to Cyclization, Hydrolysis, and Discoloration"**

The first contested term is found in subsection (a) of claim 1, "a drug component which comprises a suitable amount of an ACE inhibitor which is susceptible to cyclization, hydrolysis, and discoloration." Pejic Decl. 3d Ex. 1, col. 5:58-60. Schwarz Pharma argues that the Court is not required to construe this term because Paddock has already admitted in its Claim Chart that the drug component element of claim 1 is present in its proposed moexipril hydrochloride product. See Malone Decl. [Docket No. 58] Ex. 3.

Paddock argues that this term is in dispute and was previously construed in related

litigation in New Jersey. See Stipulation and Order, Warner-Lambert Co. v. Teva Pharm. USA, Inc. ("Warner-Lambert I"), No. 99-922, at 1-2 (D.N.J. May 8, 2002). Paddock further avers that the Federal Circuit has approved the construction given by United States District Judge Dickinson R. Debevoise in the New Jersey case. Warner-Lambert Co. v. Teva Pharm. USA, Inc. ("Warner-Lambert III"), 418 F.3d 1326, 1340 n.13 (Fed. Cir. 2005). Consequently, Paddock argues the term should be construed to mean "[a]n amount of an ACE inhibitor having antihypertensive properties having the structural capacity to cyclize via internal nucleophilic attack, hydrolyze a side chain ester, and undergo oxidative discoloration, wherein the amount of such ACE inhibitor in a drug product is sufficient (i.e., effective) to treat hypertension or congestive heart failure." The only alteration Paddock has made to the claim construction in the prior related litigation is to add "(i.e., effective)" after the word "sufficient," to clarify what is meant by a suitable amount of an ACE inhibitor.

Despite Paddock having admitted that the drug component element of claim 1 is present in its proposed moexipril hydrochloride product, the Court must still construe this term because its meaning is in dispute, as is evident by the parties inability to agree on its meaning in their joint claim construction statement. See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy."). Paddock admitted to the presence of claim 1(a) in its product based on its own interpretation of the meaning of claim 1(a), which is not necessarily the same meaning that Schwarz Pharma would attribute to claim 1(a).

Throughout its claim construction brief, Paddock argues that Schwarz Pharma is bound by Warner-Lambert's stipulation to the meaning of terms in the '450 patent in prior related

litigation, as well as the construction of claim terms in the '450 patent by the New Jersey District Court in prior related litigation that was allegedly cited with approval by the Federal Circuit. However, Paddock overstates the binding nature of these prior constructions. Schwarz Pharma was not a party to the prior stipulation entered into by Warner-Lambert and Teva Pharmaceuticals USA, Inc. ("Teva") regarding the meaning of certain claim terms in the '450 patent. See Warner-Lambert III, 418 F.3d at 1334. In addition, the stipulation specifically states that the construction of the claim terms is "to be applied in this litigation." See Warner-Lambert I, No. 99-922, at 1 (emphasis added). As a non-party to a stipulation whose effect was limited to the confines of different litigation, Schwarz Pharma is not bound by the stipulation. See Pfizer, Inc. v. Teva Pharm. USA, Inc., 429 F.3d 1364, 1376 (Fed. Cir. 2005).

Next, Schwarz Pharma is also not bound by the claim construction of the New Jersey District Court in the previous related litigation. See Order, Warner-Lambert Co. v. Teva Pharm. USA, Inc. ("Warner-Lambert II"), No. 99-922 (D.N.J. June 13, 2002). Schwarz Pharma tried to intervene in the Markman hearing, but its intervention was denied by the district court. See Schwarz Pharma, Inc. v. Teva Pharm., USA, Inc. ("Schwarz Pharma I"), No. 01-4995, at 8 (D.N.J. Mar. 24, 2003). As a non-party to the Markman hearing in New Jersey, Schwarz Pharma can not be bound by that court's construction.

Finally, while this Court is bound by the Federal Circuit's prior construction of terms in the '450 patent, the Federal Circuit has not yet construed all the claim terms that are at issue in this litigation. In Warner-Lambert III, the Federal Circuit stated in its thirteenth footnote that "we think the district court correctly construed the claims." 418 F.3d at 1340 n.13. The Federal Circuit's blanket statement regarding the district court's claim construction does not necessarily

mean that the Federal Circuit closely examined and agreed with every aspect of the district court's constructions. While the Federal Circuit's generic endorsement of the district court's constructions is an important consideration for this Court, the passing reference in a footnote does not set in stone for all time the construction of claim terms of the '450 patent whose meaning were not challenged or addressed on appeal.[6]

In the aforementioned stipulation, Warner-Lambert and Teva agreed that "a suitable amount of an ACE inhibitor which is susceptible to cyclization, hydrolysis, and discoloration" means "an amount of an ACE inhibitor having antihypertensive properties having the structural capacity to cyclize via internal nucleophilic attack, hydrolyze a side chain ester, and undergo oxidative discoloration, wherein the amount of such ACE inhibitor is sufficient to treat hypertension or congestive heart failure." Warner-Lambert I, No. 99-922, at 1-2. Paddock proposes that the Court adopt this construction in its entirety save for the addition of "(i.e. effective)" after the word "sufficient." The construction of this term is drawn from the Background section of the specification, which states:

> Certain ACE . . . inhibitors, which are useful as antihypertensives, are susceptible to certain types of degradation. Specifically, quinapril and structurally-related drugs can degrade via (1) cyclization via internal nucleophilic attack to form substituted

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[6] This Court, and the parties, are of course bound by the Federal Court's definitive construction in prior litigation of certain claim terms in the '450 patent: "discoloration" means oxidative discoloration, Warner-Lambert III, 418 F.3d at 1340; "alkali or alkaline earth metal carbonate" includes both carbonate and bicarbonate ions, Schwarz Pharma, Inc. v. Warner-Lambert Co. ("Schwarz Pharma II"), 95 Fed. Appx. 994, 997-99 (Fed. Cir. 2004); and "saccharides" includes polysaccharides, Pfizer, 429 F.3d at 1376. See Phonometrics, Inc. v. Choice Hotels Int'l, Inc., 21 Fed. Appx. 910, 912 (Fed. Cir. 2001) ("[W]e have already addressed and answered the precise question presented in this appeal. . . . Under principles of *stare decisis*, moreover, future panels like the present panel will follow the claim construction set forth by our court in [our previous decisions construing the terms of this particular patent] and, therefore, we would not welcome further appeals seeking to re-litigate the meaning of that phrase.").

> diketopiperazines, (2) hydrolysis of the side-chain ester group, and (3) oxidation to form products having often unwanted coloration.

Pejic Decl. 3d Ex. 1, col. 1:5-12. The construction proposed by Paddock gives the claim term its intended meaning, as is confirmed by the specification of the patent, without improperly narrowing or limiting the meaning of the claim term. Therefore, Paddock's proposed construction is adopted in its entirety.[7]

**3. "A Suitable Amount . . . to Inhibit Cyclization and Discoloration"**

The next term to construe is from subsection (b) of claim 1, "a suitable amount . . . to inhibit cyclization and discoloration." Pejic Decl. 3d Ex. 1, col. 5:61-63. Schwarz Pharma argues that this term means "an amount sufficient, alone or in combination with any other excipient in the formulation, to render the product FDA approvable with respect to cyclization and discoloration." Schwarz Pharma states that an excipient is "any ingredient in a pharmaceutical formulation other than the active pharmaceutical ingredient." Schwarz Pharma argues that its proposed claim construction follows the plain language of the claim and is supported by the specification. Nothing in the plain language requires the identified excipient to be solely responsible for inhibiting the identified degradation (hence, the addition of the words "or in combination with any other excipient").

Paddock construes "suitable amount" to mean "a sufficient (i.e., effective) amount to inhibit cyclization and oxidative discoloration for a given drug product; not a trace amount," and "to inhibit cyclization and discoloration" to mean "reducing cyclization and oxidative discoloration to a point that the resulting drug product is stable in accordance with generally

[7] Whether the addition of "(i.e. effective)" to the construction of this claim term is appropriate will be discussed later.

understood guidelines in existence in 1987 which would meet the requirements for FDA approval." Paddock argues that the term "a suitable amount," which appears several times throughout claims 1 and 16, should be given consistent meaning every time it appears, and the specification supports defining "suitable" to mean "effective" and "not a trace amount." Paddock supports its argument by referencing the examples in the specification, which generally show that an effective amount of alkali/alkaline earth metal carbonate is "significantly greater by weight" than the amount of ACE inhibitor. Paddock further argues that its proposed construction of "to inhibit cyclization and discoloration" is consistent with the construction determined in the related litigation.[8]

Schwarz Pharma's addition of the phrase "alone or in combination with any other excipient in the formulation" strays from the plain meaning of the claim terms and the teaching of the specification. While the meaning of the phrase in claim 1(b) "of an alkali or alkaline earth metal carbonate" is not in dispute in this litigation, it is significant that when claim 1(b) is read in its entirety, the language is "a suitable amount of an alkali or alkaline earth metal carbonate to inhibit cyclization and discoloration." Pejic Decl. 3d. Ex. 1, col 5:61-63 (emphasis added). The plain language of the claim term specifies that the alkali or alkaline earth metal is to perform the stated function of inhibiting cyclization and discoloration. Also, the use of the open transition

[8] In the related litigation, the parties stipulated that "a suitable amount" means "an amount sufficient to inhibit cyclization and discoloration," Warner-Lambert I, No. 99-922, at 2, and the New Jersey District Court found that "to inhibit cyclization and discoloration" means "reducing cyclization and discoloration to a point that the resulting drug product is stable in accordance with generally understood guidelines in existence in 1987 which would meet the requirements for FDA approval." Warner-Lambert II, No. 99-922, at 1. The Federal Circuit indicated its asset to this claim construction by stating "we think the district court correctly construed the claims." Warner-Lambert III, 418 F.3d at1340 n.13.

term "contains" in the preamble of the claim "does not free the claim from its own limitations." Kustom Signals, Inc. v. Applied Concepts, Inc., 264 F.3d 1326, 1332 (Fed. Cir. 2001).

Additionally, the specification describes the use of "excipients" as disintegrating agents, lubricants, and binders, but does not suggest that other excipients can be used to perform the function of inhibiting cyclization and discoloration. The section of the specification entitled Stabilizer(s) states:

> The cyclization and hydrolytic instability which are exhibited by certain of the drugs discussed above can be overcome via the use of a suitable quantity, i.e., an effective amount of an alkaline stabilizer, together with saccharides.
> The alkaline stabilizers of the invention include the inorganic salts of metals of Groups I and II of the Periodic Table. Thus, salts of alkali and alkaline earth metals are operable. Magnesium, calcium, and sodium are preferred. Magnesium is most preferred.
> The anionic portion of the salt employee may be any which does not deleteriously affect the stability of the overall formulation. Thus, borates, silicates, and carbonates are contemplated. Carbonates are preferred. Mixtures are operable.
> The quantity of the stabilizer component to be used will lie between about 1% and 90%, preferably about 10% to about 80%. In general, any amount which will effectively retard or prevent degradation of the ACE inhibitor component(s) can be used.

Pejic Decl. 3d Ex. 1, col. 3:25-45. The specification teaches that it is an effective amount of an alkaline stabilizer, together with saccharides, that performs the desired function of inhibiting cyclization and hydrolysis. While the exact alkaline stabilizer used in the drug product can vary with different formulations, it is the alkaline stabilizer that performs the stated function, not the alkaline stabilizer plus some other excipient.

Paddock correctly construes "suitable amount" to mean "effective" amount. The specification directly states that the suitable amount of alkaline stabilizer needed to inhibit degradation is an effective amount. Pejic. Decl. 3d Ex. 1, col. 3:27-28. Additionally, the plain language of the claim term indicates that a suitable amount of a stabilizer is an effective amount. Indeed, the entire patent is directed toward the invention of a stabilized composition of a drug

product, and therefore the invention fails if the amount of stabilizer added to the drug product is not "effective" to perform its required function.

However, Paddock stretches too far from the plain language of the terms by attempting to import the phrase "not a trace amount" into the meaning of the claim terms. Paddock correctly identifies that in the two "effective" examples set forth in the specification, the amount of magnesium carbonate in the drug product greatly outweighs the amount of quinapril hydrochloride. Pejic Decl. 3d Ex. 1, col. 4:58-70; 5:1-13. From these examples, Paddock deduces that an amount of stabilizer can not be an "effective" amount if it is a "trace amount." However, the Federal Circuit has cautioned courts not to import limitations from the specification into the claim terms. Phillips, 415 F.3d at 1323-24. Because the stated examples show a greater amount of stabilizer by weight in comparison to ACE inhibitor does not necessarily mean that all drug products falling within the ambit of the '450 patent must contain such a ratio. Cf. Rexnord Corp., 274 F.3d at 1344 ("Our case law is clear that an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention."). In addition, the specification states that "[t]he quantity of the stabilizer component to be used will lie between about 1% and 90%, preferably about 10% to about 80%. In general, any amount which will effectively retard or prevent degradation of the ACE inhibitor component(s) can be used." Pejic Decl. 3d Ex. 1, col. 3:40-45. Based on the teaching of the specification, the Court can not say with certainty that an "effective amount" of stabilizer is also "not a trace amount."

Therefore, based on the plain language of the claim terms and the teaching of the specification, "a suitable amount . . . to inhibit cyclization and discoloration" means "a sufficient

(i.e. effective) amount of an alkali or alkaline earth metal carbonate to reduce cyclization and oxidative discoloration to a point that the resulting drug product is stable in accordance with generally understood guidelines in existence in 1987 which would meet the requirements for FDA approval."

Paddock asserts that the term "a suitable amount," which appears multiple times throughout claims 1 and 16 of the '450 patent, must be construed identically each time it appears. The Court holds that "a suitable amount" means "a sufficient (i.e. effective) amount" each time it appears in the claims of the '450 patent. See Frank's Casing Crew & Rental Tools, Inc. v. Weatherford Int'l, Inc., 389 F.3d 1370, 1377 (Fed. Cir. 2004) ("[T]he same terms appearing in different portions of the claims should be given the same meaning unless it is clear from the specification and prosecution history that the terms have different meanings at different portions of the claims."). This meaning is discerned from the plain language of the claim terms as well as the teaching of the specification. The invention of the patent is directed to stabilized compositions of certain drug products. The key ingredients in the drug products, namely the ACE inhibitors and stabilizers, are necessary because they perform the stated desirable functions. If the key ingredients were not effective at performing the stated desirable functions, then they would not be needed in the resulting drug product.

Further, it is immaterial that the word "effective" does not appear in the section of the specification entitled Drug Component(s). The phrase "a suitable amount" was not added to claim 1(a) of the '450 patent until after the patent was initially rejected by the patent examiner for obviousness. Pejic Decl. 3d Exs. 5-8. The patent was granted only after a responsive amendment by the patentee, and the phrase "a suitable amount" was added as an examiner's

amendment to modify the phrase "of an ACE inhibitor." Id. Exs. 7-8. It follows logically that the patent examiner intended by his amendment to assert that "a suitable amount of an ACE inhibitor" is an "effective amount." See Phillips, 415 F.3d at 1314 ("Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims.").

**4. "A Suitable Amount . . . to Inhibit Hydrolysis"**

The next term to construe is found in subsection (c) of claim 1 and reads "a suitable amount . . . to inhibit hydrolysis." Pejic Decl. 3d Ex. 1, col. 6:1-2. Schwarz Pharma construes this term as "an amount sufficient, alone or in combination with any other excipient in the formulation, to render the product FDA approvable with respect to hydrolysis." Schwarz Pharma asserts that this term has a similar meaning to the claim term previously discussed, and for the same reasons. By contrast, Paddock construes this term to mean "a sufficient (i.e., effective) amount of a saccharide to reduce hydrolysis to a point that the resulting drug product is stable in accordance with generally understood guidelines in existence in 1987 which would meet the requirements for FDA approval." Paddock asserts that it construes this term, as it did with the previous similar term, to follow the construction from related litigation.[9]

This claim term is identical to the previously construed claim term except that a different

[9] Again, in the related litigation, the parties stipulated that "a suitable amount" means "an amount sufficient to inhibit hydrolysis," Warner-Lambert I, No. 99-922, at 2-3, and the New Jersey District Court found that "to inhibit hydrolysis" means "reducing hydrolysis to a point that the resulting drug product is stable in accordance with generally understood guidelines in existence in 1987 which would meet the requirements for FDA approval." Warner-Lambert II, No. 99-922, at 1-2. The Federal Circuit indicated its assent to this claim construction by stating "we think the district court correctly construed the claims." Warner-Lambert III, 418 F.3d at1340 n.13.

type of degradation is inhibited by a different type of substance, namely, a saccharide. Consequently, the Court construes this term consistently with the construction of the previous nearly identical term and for the same reasons. Paddock's construction of the term is adopted. "A suitable amount . . . to inhibit hydrolysis" means "a sufficient (i.e., effective) amount of a saccharide to reduce hydrolysis to a point that the resulting drug product is stable in accordance with generally understood guidelines in existence in 1987 which would meet the requirements for FDA approval."

**5. "A Process for Stabilizing"**

The next term to construe is from claim 16, "a process for stabilizing." Pejic Decl. 3d Ex. 1, col. 6:54-56. Schwarz Pharma alleges that there is no dispute regarding the meaning of this claim term because Paddock admits that it will practice "a process for stabilizing," and Paddock fails to challenge the validity of the claim. Paddock construes the language to mean "a method of making a pharmaceutical dosage form of an ACE inhibitor in which cyclization has been inhibited." Paddock asserts that its claim construction is consistent with that used in the related litigation, and Schwarz Pharma should be bound by the previous construction.[10]

As discussed with regard to the first claim term, Paddock's agreement that it will practice "a process for stabilizing" does not mean that the parties agree as to what the term means, or that the Court can not construe it. The parties failed to agree to the meaning of the term in the Joint Claim Construction Statement. The purpose of the '450 patent is ultimately to create an

[10] In the related litigation, the New Jersey District Court found that "a process for stabilizing" means "a method of making a pharmaceutical dosage form of an ACE inhibitor in which cyclization has been inhibited." Warner-Lambert II, No. 99-922, at 2. Teva did not appeal the district court's grant of summary judgment of infringement with respect to claim 16. Warner-Lambert III, 418 F.3d at 1339 n.12.

effective dosage form of an ACE inhibitor in which cyclization and hydrolysis are inhibited. However, the "Description of the Invention" section of the specification distinguishes the "pharmaceutical composition," the "process for stabilizing," and the "method of making a pharmaceutical dosage form:"

> The invention deals with:
> I. A pharmaceutical composition which contains:
> (a) a drug component which comprises an ACE inhibitor which is susceptible to retard cyclization, hydrolysis, and/or discoloration, and
> (b) an amount of a stabilizer component or components suitable to retard cyclization, hydrolysis, and/or discoloration, and
> II. A process for stabilizing an ACE inhibitor drug which comprises the step of contacting the drug with:
> (a) an amount of stabilizer(s) suitable to retard cyclization and/or hydrolysis.
> III. A method of making a pharmaceutical dosage form which comprises the step of including in the formulation suitable amounts of:
> (a) an ACE inhibitor, and
> (b) stabilizers which contain alkaline agents alone or alkaline agents in combination with saccharides (i.e., sugars) as one or more cyclization, hydrolysis, and discoloration inhibitor(s).

Pejic Decl. 3d Ex. 1, col. 1:44-63. Claim 16 does not appear to be directed toward making a particular dosage form. Therefore, there is no need to import a limitation regarding "a pharmaceutical dosage form" into claim 16. The term "a process for stabilizing" is construed as "a method of making a drug product containing an ACE inhibitor in which cyclization has been inhibited."

**6. "A Suitable Amount of"**

The next term to construe is found in subsection (a) of claim 16, "a suitable amount of." Pejic Decl. 3d Ex. 1, col. 6:57-58. Schwarz Pharma construes this term similarly to its construction of this term in claim 1, and pursuant to the alleged context of the claim: "an amount sufficient, alone or in combination with any other excipient in the formulation, to render the

product FDA approvable with respect to cyclization." Paddock's construction is "an amount of an alkali or alkaline earth metal carbonate sufficient (i.e. effective) to inhibit cyclization in a dosage form." Paddock argues that this construction is consistent with the related litigation,[11] and the examples in the specification which show that an amount of carbonate "significantly greater" than the amount of ACE inhibitor is needed.

As stated above, the same term repeated throughout the same claim and different claims in the same patent should be construed to have the same meaning. Consequently, the term "a suitable amount" means "an amount sufficient (i.e. effective) of an alkali or alkaline earth metal carbonate to inhibit cyclization to a point that the resulting drug product is stable in accordance with generally understood guidelines in existence in 1987 which would meet the requirements for FDA approval."

**7. "One or More Saccharides"**

The final term to construe is found in subsection (b) of claim 16, "one or more saccharides." Pejic Decl. 3d Ex. 1, col.6:59. Schwarz Pharma construes this term to mean "[t]he process must involve the use of at least one saccharide. There is no requirement that the saccharide perform any particular function in the process or formulation." Paddock's construction is "a saccharide or saccharides which are a component of a dosage form of an ACE inhibitor in which cyclization has been inhibited." Paddock again avers its construction is

[11] In the related litigation, the parties stipulated that "a suitable amount" means "an amount sufficient to inhibit cyclization." Warner-Lambert I, No. 99-922, at 4. Teva did not appeal the district court's grant of summary judgment of infringement with respect to claim 16. Warner-Lambert III, 418 F.3d at 1339 n.12.

consistent with that used in the prior litigation.[12]

This Court agrees with New Jersey District Court Judge Debevoise's construction and analysis of the instant claim term. See Warner-Lambert II, No. 99-922, at 17. The plain language of the claim terms, read in conjunction with the entire specification, make clear that the function of the saccharide in the pharmaceutical composition is to inhibit hydrolysis. Claim 16 does not speak to the functioning of the saccharide. Pejic Decl. 3d Ex. 1, col 6:54-59. This does not mean, however, that the saccharide performs no function with respect to the pharmaceutical composition, as claim 1 and the specification state that the saccharide performs the function of inhibiting hydrolysis. It simply means that claim 16 does not speak to the function of the saccharide, and therefore the claim construction propounded by the New Jersey District Court and proposed by Paddock is adopted, with the exception that "drug product" is substituted for "dosage form:" "a saccharide or saccharides which are a component of a drug product containing an ACE inhibitor in which cyclization has been inhibited."

**B. Paddock's Summary Judgment Request**

Paddock has filed a Motion for Leave to File a Motion for Summary Judgment, as required by this Court's September 1, 2005 Order. Paddock argues its ANDA could receive approval from the FDA as early as May-June 2006. Consequently, Paddock argues it should be allowed to file a summary judgment motion after service of Plaintiffs' Expert Report(s) so that the purposes of the Hatch-Waxman Act are not frustrated and irreparable harm to Paddock does

[12] In the related litigation, the New Jersey District Court found that "one or more saccharides" means "a saccharide or saccharides which are a component of a dosage form of an ACE inhibitor in which cyclization has been inhibited." Warner-Lambert II, No. 99-922, at 2. Teva did not appeal the district court's grant of summary judgment of infringement with respect to claim 16. Warner-Lambert III, 418 F.3d at 1339 n.12.

not occur. Paddock also argues that it has now provided Plaintiffs with sufficient discovery to oppose a summary judgment motion.

Paddock's Motion for Leave is denied. Paddock's argument is that if it could resolve this lawsuit now, it would be ready and able to produce and market its generic moexipril product as soon as its ANDA receives FDA approval. This argument, however, presumes an outcome in Paddock's favor, which is not a foregone conclusion. The Court previously stated that if Paddock's ANDA received tentative approval before the close of discovery, Paddock could petition for leave to file a summary judgment motion. There is nothing in the record to suggest Paddock's ANDA has received tentative approval. Nothing has changed, and Paddock's speculative contentions do not serve as a basis to reverse the prior decision.

**C. Objections to Magistrate Judge Graham's Order**

Warner-Lambert objects to the portion of Magistrate Judge Graham's Order that compels Warner-Lambert to respond to Paddock's requests for admission. Judge Graham Order ¶ 10. Warner-Lambert argues that it owns the patent-in-suit and was named an involuntary plaintiff in this action by Schwarz Pharma, its exclusive licensee. Warner-Lambert itself has not made any allegations of infringement against Paddock, and therefore answering requests for admission can serve no legitimate purpose because the answers will not narrow any issues between Warner-Lambert and Paddock for trial, they are not evidence, and they are not admissible against Schwarz Pharma. Beyond the issue of admissions, Warner-Lambert does not dispute that it must participate in discovery.

Paddock responds that Warner-Lambert is not an involuntary plaintiff because it has voluntarily availed itself of the jurisdiction of this Court. Also, Warner-Lambert's admissions

would narrow factual issues because the admissions are binding with respect to factual matters relating to the '450 patent, the prosecution history, the subject matter claimed therein, and the knowledge of the named inventors. The requests for admission are properly directed to Warner-Lambert because they concern information within Warner-Lambert's possession or control.

In reviewing a magistrate judge's non-dispositive pre-trial order, the district court "shall consider such objections and shall modify or set aside any portion of the Magistrate Judge's order found to be clearly erroneous or contrary to law." 28 U.S.C. § 636(b)(1)(A); Fed. R. Civ. Pro. 72(a); D. Minn. LR 72.2(a). Rule 36(a) of the Federal Rules of Civil Procedure states

> [a] party may serve upon any other party a written request for the admission, for purposes of the pending action only, of the truth of any matters within the scope of Rule 26(b)(1) [concerning general discovery scope and limits] set forth in the request that relate to statements or opinions of fact or of the application of law to fact, including the genuineness of any documents described in the request.

The Rule also describes the process for answering and the effect of requests for admission. The Advisory Committee Notes to Rule 36 state "[r]ule 36 serves two vital purposes, both of which are designed to reduce trial time. Admissions are sought, first to facilitate proof with respect to issues that cannot be eliminated from the case, and secondly, to narrow the issues by eliminating those that can be."

Magistrate Judge Graham determined that Warner-Lambert is not an involuntary plaintiff in this matter because it has voluntarily availed itself of the Court's jurisdiction. See Cilco, Inc. v. Precision-Cosmet, Inc., 624 F. Supp. 49, 51-52 (D. Minn. 1985) (reciting four-part test for determining involuntary plaintiff status), citing Indep. Wireless Tel. Co. v. Radio Corp. of Am., 269 U.S. 459 (1926); see also Notification of Appearance of Counsel [Docket No. 49]. Regardless, as parties to this action, Paddock may serve requests for admission upon Warner-

Lambert for the purpose of narrowing issues for trial or facilitating proof of the remaining issues. Whether Warner-Lambert has asserted an infringement position or if the admissions are binding on Schwarz Pharma are irrelevant—Warner-Lambert's admissions may still narrow the issues between the parties for trial. Judge Graham's Order was not clearly erroneous or contrary to law; therefore, Warner-Lambert's Objections are overruled.

## IV. CONCLUSION

Based upon the foregoing, and all of the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that:

1. In interpreting the '450 patent, the contested terms be construed in accordance with this Order;

a. In claim 1(a) of the '450 patent, the term "a drug component which comprises a suitable amount of an ACE inhibitor which is susceptible to cyclization, hydrolysis, and discoloration" means "an amount of an ACE inhibitor having antihypertensive properties having the structural capacity to cyclize via internal nucleophilic attack, hydrolyze a side chain ester, and undergo oxidative discoloration, wherein the amount of such ACE inhibitor in a drug product is sufficient (i.e., effective) to treat hypertension or congestive heart failure;"

b. In claim 1(b) of the '450 patent, the term "a suitable amount . . . to inhibit cyclization and discoloration" means "a sufficient (i.e. effective) amount of an alkali or alkaline earth metal carbonate to reduce cyclization and oxidative discoloration to a point that the resulting drug product is stable in accordance with generally understood guidelines in existence in 1987 which would meet the requirements for FDA approval;"

c. In claim 1(c) of the '450 patent, the term "a suitable amount . . . to inhibit hydrolysis" means "a sufficient (i.e., effective) amount of a saccharide to reduce hydrolysis to a point that the resulting drug product is stable in accordance with generally understood guidelines in existence in 1987 which would meet the requirements for FDA approval;"

d. In claim 16 of the '450 patent, the term "a process for stabilizing" means "a method of making a drug product containing an ACE inhibitor in which cyclization has been

inhibited;"

e. In claim 16(a) of the '450 patent, the term "a suitable amount" means "an amount sufficient (i.e. effective) of an alkali or alkaline earth metal carbonate to inhibit cyclization to a point that the resulting drug product is stable in accordance with generally understood guidelines in existence in 1987 which would meet the requirements for FDA approval;"

f. In claim 16(b) of the '450 patent, the term "one or more saccharides" means "a saccharide or saccharides which are a component of a drug product containing an ACE inhibitor in which cyclization has been inhibited;"

2. Paddock's Motion for Leave to File a Motion for Summary Judgment of Noninfringement [Docket No. 120] is **DENIED**; and

3. Warner-Lambert's Objections [Docket No. 88] to Magistrate Judge Jeanne J. Graham's Order [Docket No. 86] are **OVERRULED**.

BY THE COURT:

s/Ann D. Montgomery
ANN D. MONTGOMERY
U.S. DISTRICT JUDGE

Dated: April 18, 2006.